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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,114

02/25/2004

Masaaki Goto

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EXAMINER

DUTT, ADITI

ART UNIT

PAPER NUMBER

1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/785,114	<b>Applicant(s)</b> GOTO ET AL.	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

-- The **MAILING DATE** of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 32-48 is/are pending in the application.
- 4a) Of the above claim(s) 41-43, 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-40, 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-48 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Claims*

1. The amendment filed on 27 October 2006 has been entered into the record and has been fully considered. Claims 32-37 are amended.
2. New claims 38-48 have been added.
3. Claims 32-40 and 44-46 are under consideration in the instant application. The claims are drawn to a method of improving decreased bone mass or density by administering in humans: a) a pharmaceutical preparation containing 'an' OCIF protein encoded by SEQ ID NO: 6, or 'an' OCIF protein encoded by a nucleic acid molecule that hybridizes with another nucleic acid molecule having SEQ ID NO: 6 (claims 32, 35); b) a pharmaceutical preparation for introducing 'an' OCIF protein encoded by SEQ ID NO: 6, or 'an' OCIF protein encoded by a nucleic acid molecule that hybridizes with another nucleic acid molecule having SEQ ID NO: 6 (claims 33, 36); c) 'an' OCIF protein encoded by SEQ ID NO: 6, or 'an' OCIF protein encoded by a nucleic acid molecule that hybridizes with another nucleic acid molecule having SEQ ID NO: 6 (claims 34, 37). The claims further recite oral or parenteral administration of the pharmaceutical preparation (claims 38-40, 44-46). It is noted that the Examiner has broadly interpreted the phrases "an OCIF protein encoded by SEQ ID NO: 6" (claims 32-34, 38-40) and "an OCIF protein" encoded by a nucleic acid molecule that hybridizes with

another nucleic acid molecule having SEQ ID NO: 6 (claims 35-37, 44-46) to encompass any OCIF protein, variant, or fragment.

4. Claims 41-43 and 47-48, are withdrawn from further consideration, based upon the election by original presentation. Newly submitted claims 41-43 and 47-48, directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
5. The claims recite amino acid sequences that represent unique proteins encoded by unique nucleic acid sequences and requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.
6. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-43 and 47-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
7. The text of any section of 35 U.S.C. not reiterated in this office action can be found in a previous office action.
8. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
9. Applicant's arguments filed on 27 October 2006, have been fully considered. New grounds of objection and rejection are as follow.

***Response to Amendment***

Withdrawn objections and/or rejections

10. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (27 October 2006).
11. Rejection of claims 32-36 under 35 U.S.C. 112, second paragraph is withdrawn, in light of the argument presented by the Applicant, which was persuasive.

Claim rejections/objections maintained/new grounds of rejection

112, first paragraph (Scope of Enablement)

12. The rejections of claims 32-37 are applied to the amended claims (32-37) and new claims 38-40 and 44-46, for reasons of record in the Office Action dated 27 July 2006.
13. Applicant argues that since the OCIF protein of SEQ ID NO: 5 is enabled, it would necessarily follow that the method of increasing bone mass by administering an OCIF protein encoded by SEQ ID NO: 6 is also enabled. Applicant further asserts that no scientific or legal basis was provided to support the assertion based on the interpretation of the phrase "an OCIF protein".

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14. Applicant's arguments have been fully considered but have not been found to be persuasive. A prima facie case of scope of enablement was made in the previous Office Action dated 27 July 2006, pages 4-8. See also points below:
15. The specification does not teach functional or structural characteristics of the fragments and variants of OCIF recited in the claims other than the polypeptide comprising the full-length and "mature" amino acid sequence of SEQ ID NO: 5. It is not clear from the relevant pre and post-filing date literature as to what regions of the OCIF sequences or the maximum length of the sequences are essential for biological activity. Thus, undue experimentation would be required of the skilled artisan to identify the precise structural characteristics of OCIF fragments and variants showing inhibition of bone resorption activity.
16. Due to the large quantity of experimentation necessary to generate the infinite number of OCIF fragments and variants recited in the claims and screen the same for improvement of decreased bone mass activity; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function; and the breadth of the claims which fail to recite any structural or functional limitations - undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.
17. This issue could be overcome by replacing 'an' with 'the'.

112, first paragraph – Written Description

18. The rejections of claims 32-37 are applied to the amended claims (32-37) and new claims 38-40 and 44-46, for reasons of record in the Office Action dated 27 July 2006.
19. Applicant argues that based upon the chemical sequence listing, the functional and physical properties of OCIF proteins encoded by SEQ ID NO: 6, provided in the instant specification, Applicants were in possession of the claimed invention. Furthermore, the Applicant repeats the assertion that since the

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OCIF protein of SEQ ID NO: 5 is enabled, it would necessarily follow that the method of increasing bone mass by administering an OCIF protein encoded by SEQ ID NO: 6 is also enabled. Applicant cites case law to support the argument of a representative number of species.

20. Applicant's arguments have been fully considered but have not found to be persuasive, because the brief description in the instant specification is directed to the mature full-length protein, not to the entire genus of fragments or variants. As stated in the previous Office Action:
21. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The specification has not shown a relationship between the structure, function, or properties of the claimed genus of polypeptides. However, in this case, the only factor present in the claim is a recitation of functional activity. There is not even identification of any particular portion of the OCIF structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.
22. Furthermore, claims 35-37 have been amended to recite hybridization limitation to the OCIF proteins. Applicant's arguments have been fully considered but have not been found to be persuasive. Addition of hybridization details is not a valid limitation to claims directed to polypeptides. Furthermore, even if the claims were amended such that the proteins encoded by the amino acids were identified by hybridization, they would still encompass variants with no required structural or functional characteristics and thus would still not be adequately described by the specification.

Double patenting

23. The rejections of claims 32-37 are applied to the amended claims (32-37), for reasons of record in the Office Action dated 27 July 2006.
24. Applicant argues that the Examiner has provided no evidence that claims 32-37 are obvious in view of claims 32-33, 35-36 of co-pending Application No. 10/979,654. However, Applicant agrees to consider the submission of a Terminal Disclaimer upon indication of allowable subject matter.
25. Applicant's arguments have been fully considered but have not found to be persuasive, because of the reasons stated in the previous Office Action. The rejection will be maintained of record until the submission of the disclaimer.

***Claim Rejections - 35 USC § 112***

26. Claims 35-37, 44-46, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
27. Claims 35-37, 44-46 are vague and unclear, because the nucleic acid encoding the OCIF protein is SEQ ID NO: 6, not its complement, therefore, will not be able to hybridize to itself.



***Status of Claims***

28. No claims are allowed.
29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
30. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.
31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
03 January 2007

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER